MEIJER CHILDRENS PAIN AND FEVER REDUCER- acetaminophen tablet, chewable MEIJER DISTRIBUTION INC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Children's Pain and Fever Chewables Acetaminophen

Active ingredient (in each chewable tablet)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - flu
 - headache
 - sore throat
 - toothache
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen.

Allergy Alert:

acetaminophen may cause severe skin reaction. Symptom may include:

- skin reddening
- blister
- rash
- If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning:

If sore throat is severe, persists for more than 2 days is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if your child has

liver disease.

Ask a doctor or pharmacist before use if your child is

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use.
- do not give more than directed (see overdose warning)
- find the right dose on chart below. If possible, use weight to dose; otherwise use age.
- · chew completely do not swallow whole
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight	under	24-35	36-47	48-59	60-71	72-95
(lbs)	24					

Age (yr)	under 2	2-3	4-5	6-8	9-10	11
	years	years	years	years	years	years
Dose	ask a	1	1 ½	2	2 ½	3
(tablets)*	doctor	tablet	tablets	tablets	tablets	tablets

Other information

- store at room temperature. Avoid high humidity. Protect from light.
- see end flap for expiration date and lot number

Inactive ingredients

citric acid, crospovidone, D&C Red No. 30, dextrose, flavor, hydroxypropylcellulose, magnesium stearate, maltodextrin, silicon dioxide, sodium carboxymethylcellulose, starch, sucralose.

Questions or comments?

1-866-467-2748

Principal Display Panel

NDC 41250-246-24

Compare to active ingredient in Children's Tylenol® Chewables*

Children's

Pain + Fever Chewables

Acetaminophen 160 mg each

Pain reliever/Fever reducer

Aspirin free

Ibuprofen free

AGES 2-11

Bubblegum Flavor

Naturally and Artificially Flavored

24 Chewable Tablets - 160 mg each

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Children's Tylenol® Chewables.

IMPORTANT: Keep this carton for future reference on full labeling.

Distributed by:
MEIJER DISTRIBUTION INC
GRAND RAPIDS, MI, 49544
www.meijer.com



MEIJER CHILDRENS PAIN AND FEVER REDUCER

acetaminophen tablet, chewable

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-246		
Route of Administration	ORAL				

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	160 mg			

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPOVIDONE (120 .MU.M) (UNII: 68401960MK)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics				
Color	PINK	Score	2 pieces	
Shape	ROUND	Size	16mm	
Flavor	BUBBLE GUM	Imprint Code	RP160	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41250-246- 24	4 in 1 CARTON	01/29/2020			
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing I	nformation		
Marketing	Application Number or Monograph	Marketing Start	Marketing End
Marketing	Application Number or Monograph	Marketing Start	магкет

Category	Citation	Date	Date
OTC monograph not final	part343	01/29/2020	

Labeler - MEIJER DISTRIBUTION INC (006959555)

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